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Abstract: Background: Disorders of the respiratory transition at birth are major reasons for neonates being admitted to intensive care units and separated from their mothers. This has potential long-lasting consequences for the mother-infant interaction as well as the long-term development of the child. There is an urgent need for effective preventive and therapeutic measures for this frequent disorder. Case Report: We report the cases of 2 newborn infants with respiratory transitional disorder treated offlabel with the anthroposophic medicament Pulmo/Vivianit comp. based on pathophysiological considerations and on particular parental request. In both cases, an immediate and sustainable response could be documented without adverse effects. Conclusion: This new therapeutic approach merits further attention in clinical research but cannot be recommended for routine practice before more high-level evidence is available.

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# Successful Treatment of Neonatal Respiratory Transitional Disorder with Pulmo/Vivianit comp. in 2 Cases

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**Keywords**
Respiratory transition · Respiratory distress syndrome · Neonatology · Mother-infant separation · Pulmo/Vivianit comp. · Anthroposophic medicine

**Schlüsselwörter**
Respiratorische Adaptation · Atemnotsyndrom · Neonatologie · Mutter-Kind-Trennung · Pulmo/Vivianit comp. · Anthroposophische Medizin

**Summary**
**Background:** Disorders of the respiratory transition at birth are major reasons for neonates being admitted to intensive care units and separated from their mothers. This has potential long-lasting consequences for the mother-infant interaction as well as the long-term development of the child. There is an urgent need for effective preventive and therapeutic measures for this frequent disorder. **Case Report:** We report the cases of 2 newborn infants with respiratory transitional disorder treated off-label with the anthroposophic medicament Pulmo/Vivianit comp. based on pathophysiological considerations and on particular parental request. In both cases, an immediate and sustainable response could be documented without adverse effects. **Conclusion:** This new therapeutic approach merits further attention in clinical research but cannot be recommended for routine practice before more high-level evidence is available.


**Zusammenfassung**
**Hintergrund:** Störungen der respiratorischen Adaptation bei Geburt sind Hauptgründe für die Aufnahme von Neugeborenen auf die Intensivstation und die Trennung von ihren Müttern. Damit sind potenziell langfristige Folgen für die Mutter-Kind-Interaktion sowie die Langzeitentwicklung des Kindes verbunden. Es besteht ein dringender Bedarf an wirksamen präventiven und therapeutischen Maßnahmen zur Behandlung dieses häufigen Problems. **Fallbericht:** Wir berichten über 2 Fälle von Neugeborenen mit respiratorischer Adaptationsstörung, die auf der Grundlage von pathophysiologischen Überlegungen und auf besonderen Wunsch der Eltern off-label mit dem anthroposophischen Medikament Pulmo/Vivianit comp. behandelt wurden. In beiden Fällen konnte ein unmittelbares und nachhaltiges Ansprechen ohne unerwünschte Wirkungen dokumentiert werden. **Schlussfolgerung:** Dieser neue therapeutische Ansatz verdient weitere Aufmerksamkeit in der klinischen Forschung, er kann aber erst dann für die Routineanwendung empfohlen werden, wenn höhere Evidenz verfügbar ist.

## Introduction

Postpartum separation of the mother and her baby affects the maternal attachment, breastfeeding and the physiological adaptation of both the mother and the newborn infant [1]. A randomized controlled trial demonstrated detrimental effects of an early mother-infant separation on the mother-infant interaction even 1 year later [2]. Therefore, future strategies should focus on keeping mother and baby together and on reducing separation due to medical reasons during the neonatal period to a minimum.

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Acute respiratory disorders are major reasons for neonates being separated from their mothers and admitted to the neonatal intensive care unit (NICU) after birth. In particular, neonates delivered by elective caesarean section have an increased risk of respiratory morbidity [3]. The current management mainly focuses on respiratory support, while no effective pharmacological treatment specifically promoting the functional changes of the respiratory transition could be established so far [4].

In addition to potential consequences for the mother-infant interaction, neonatal respiratory disorders are a risk factor for the long-term development of the child either due to the disease itself or due to complications of the intensive care management [5]. The frequency of these disorders as well as the associated economic burden for the health care systems warrants research for new therapeutic approaches helping to avoid or shorten the NICU hospitalization. This should not be restricted to already known pharmaceutical products but should cover all fields, including integrative and complementary medicine.

We report 2 cases of respiratory transitional disorder following caesarean section. Both infants were treated off-label with the anthroposophic medication Pulmo/Vivianit comp. (WALA® Heilmittel GmbH, Bad Boll/Eckwälden, Germany) and mother-infant separation could be avoided. This treatment trial was made possible due to the explicit request and consent of the parents and because of the particular hospital setting with continuous monitoring in the well-baby nursery and a complete NICU backup in the same unit.

Pulmo/Vivianit comp. was originally developed for the treatment of pneumonia [6]. It is composed of 4 constituents, with normal saline serving as solvent: the minerals Tartarus stibiatus D7 and Vivianite D7, the plant *Bryonia cretica* D5, and the animal organ preparation Pulmo D16 of a bovine lung. Each of the potentized components and the final composition of the product are prepared according to the anthroposophic pharmaceutical codex, which guarantees good manufacturing practice and pharmaceutical safety issues [7]. The medication is officially registered and licensed by the respective regulatory bodies in Germany (Federal Institute for Drugs and Medical Devices) and Switzerland (Swissmedic). The therapeutic properties are attributed to the stimulation of lung development and regeneration, regulation of the pulmonary fluid balance, and the coordination of lung ventilation and perfusion optimizing gas exchange [6, 8].

Scientific evidence for Pulmo/Vivianit comp. is limited to expert opinions and case reports [8–11]. These suggest effectiveness in the treatment of pulmonary disorders in children and adults without indication of adverse effects or safety problems. As these disorders comprise pathophysiologic alterations on a functional level comparable to the transitional changes during pulmonary adaptation at birth, we hypothesized a possible effect of Pulmo/Vivianit comp. in the treatment of neonatal respiratory transitional disorders.

## Case Reports

*Case 1*

A newborn girl had persistent signs of respiratory distress at the age of 8 h. The pregnancy, the delivery by caesarean section at gestational week 39 4/7 because of breech presentation, and the primary adaptation were uneventful (umbilical artery pH 7.30, Apgar 9/10/10, birth weight 3,540 g). On examination, she was laying in prone position in skin-to-skin contact on the mother's chest. Leading symptoms were loud grunting, nasal flaring, and subcostal retractions. The respiratory rate and oxygen saturation (SpO2) without supplemental oxygen were normal. The baby was awake, but her eyes were closed and no spontaneous movements despite increased work of breathing could be observed. There was no further indication of perinatal infection.

Assuming respiratory distress following delayed pulmonary transition after caesarean section, an attempt was made to specifically support the respiratory transition with Pulmo/Vivianit comp. This could be performed immediately without separating the baby from the mother. The solution was administered orally 3 times 5 drops at 5-min intervals. Beginning already 1 min after the first application, the signs of respiratory distress improved continuously and ceased completely after 15 min.

Because of this rapid and complete recovery there was no need for further investigations and the baby could stay with the mother. Under close monitoring, no relapse of respiratory distress and no adverse treatment events occurred until discharge on day 5. In retrospect, the parents were satisfied and grateful that the respiratory disorder after birth could be resolved without separation of mother and baby and without painful (blood sampling) or harmful (radiographic imaging) investigations of their child.

*Case 2*

Twin boys were delivered by caesarean section at the gestational age of 35 5/7 weeks, after premature rupture of membranes of the leading twin. There were no signs or risk factors of perinatal infection. The birth weight was 2,450 and 2,350 g, Apgar was 8/9/10 and 7/8/9, and the umbilical artery pH was 7.22 and 7.21, respectively.

Only the second twin showed progressive signs of respiratory distress with strong grunting, nasal flaring, subcostal retractions, tachypnea and need for supplemental oxygen (fraction of inspired oxygen (FiO2) maximum 0.45) due to a persistent low SpO2 around 80% under room air at the age of 10 min. Apart from the respiratory disorder, other vital signs and a complete physical examination were normal. The respiratory disorder persisted to the age of 30 min and a decision had to be made concerning transfer of the boy to the NICU for continuous respiratory support and monitoring.

In this situation, a therapeutic trial was made to support the infant's own effort in managing the respiratory transition. Pulmo/Vivianit comp. was given orally 3 times 5 drops at 5-min intervals. An immediate response with gradual improvement of the respiratory symptoms could be observed within minutes. The grunting decreased and stopped intermittently; the SpO2 increased to values above 96% even after reducing the FiO2 to finally 0.21 (room air). 20 min after the first dose of Pulmo/Vivianit comp., only a tachypnea of 80/min (reference range 40–60/min) persisted as a residual finding of the respiratory distress. Thus, clinical observation with monitoring of the SpO2 and respiratory symptoms gave sufficient information and further diagnostic tests could be omitted. At the age of 2 h, breathing had normalized and a transfer of both twins together with their mother to the well-baby nursery was possible. The regular controls following premature birth were completely normal, without indication of respiratory problems or adverse reactions until discharge after 1 week.

## Discussion

Both cases are highly representative of postnatal respiratory distress caused by an impaired respiratory transition from intrauterine to extrauterine life [4, 12]. The treatment was performed only

with Pulmo/Vivianit comp., and an immediate effect could be observed. The pattern of improvement corresponded exactly to the natural course of delayed respiratory transition, with increased work of breathing at the beginning and tachypnea only at the end of the symptomatic period. Yet, following the application of Pulmo/Vivianit comp., the duration of the respiratory disorder was markedly reduced and an admission to the NICU with consecutive separation from the mother could be avoided. Along with the respiratory improvement, both infants became more active and interactive, regular movements were established, feeding and digestive functions improved, and normal diuresis started. Finally, no adverse effects of the treatment occurred in both cases.

Case reports provide a low level of evidence as assessment and generalizability of the observed treatment effect are limited. However, to distinguish it from a spontaneous recovery and to judge on the probability of a true association between the therapeutic intervention and the observed outcome in our cases, some criteria can be stated: (1) the duration and severity of the respiratory disorder and its relation to the timing of the response with prompt and marked improvement within minutes, (2) the absence of co-interventions, (3) long-lasting normalization of respiration and the overall functional state of the babies, (4) consistency among both cases, (5) the specific and predicted outcome following the intervention, and finally (6) the confirmation of the idea of specifically supporting the infants' own regulative forces in managing the disorder by the fact that the observable development after the medication resembles exactly the natural course of the disease, albeit in an accelerated mode. One needs to keep in mind that all currently established therapies started with single case reports, sometimes even before the pharmacological mechanisms of action had been discovered.

The need for research on preventive and therapeutic interventions covers pharmaceutical agents stimulating the transitional changes in the respiratory system at birth. This includes glucocorticoids, inhaled epinephrine, inhaled salbutamol, diuretics, and oral or aerosolized furosemide [4]. Despite promising concepts, none of these agents achieved sufficient evidence from clinical trials to gain access to routine clinical practice. According to the encouraging results presented here, the treatment of respiratory transitional disorders with Pulmo/Vivianit comp. merits further attention in clinical practice and research. It is based on the physiology of the respiratory transition and its disorders on a functional level [12]. It could help to avoid admission and separation of affected neonates as well as complement the conventional respiratory support in the NICU in order to reduce the morbidity and mortality of this frequent disorder. Currently, the treatment of respiratory transitional disorders in newborns with Pulmo/Vivianit comp. should be considered experimental. More high-level evidence research is warranted before it can be recommended for routine practice in neonatology. In addition, further controlled studies should not only focus on effectiveness but also on safety issues in this vulnerable population.

## Disclosure Statement

The authors declare that they have no conflict of interest.

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